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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/802,280

03/17/2004

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08/23/2006

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

CLAIMS 1-53 ARE PRESENTED FOR EXAMINATION

Applicants' Reply to Office Action filed June 9, 2006 has been received and entered into the application. Accordingly, claims 1, 16, 25, 34, 44 and 48-50 have been amended.

In view of such amendments, as well as Applicants' remarks at pages 10-11 of their Reply, the rejection of claims 34-43 under 35 U.S.C. § 112, first paragraph and of claims 1-6, 10, 16-21, 25-30 and 34-40 under 35 U.S.C. § 102(b), as being anticipated by Okamoto et al., as set forth in the previous Office action dated March 31, 2006 at pages 2-9 and 11-13, are each withdrawn.

Claim Objections

Claims 48-50 remain objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, for the reasons of record as set forth in the previous Office action at page 2.

Applicants amendments to claims 48-50 and remarks at page 10 of their Reply have been carefully considered, but fail to persuade the Examiner of error in his determination.

By amendment, Applicants have indicated that the prescribing information contained in the kit of claim 40 includes specific information for the patient concerning the administration of the claimed designated compound.

Such is not deemed to be further limiting of the kit of claim 40, which provides for prescribing information, because the written material on the prescribing information is not subject to patent laws, or at the least is only a statement of intended use, and thus does not impart any further physical or otherwise material feature to the kit of claim 40. Such would be considered a further

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limitation if the written material were not simply matter printed on the substrate, but rather were of a type of written material such as the digits imprinted on the band of a mathematical device considered in the decision of *In re Gurlack*, 217 USPQ 401 (CAFC 1983). Also, while written material may properly be recited in a claim, as noted above, the specific printed information is not material covered under patent laws, but rather copyright laws. In this respect, because such matter is not statutory, it is not seen as further limiting subject matter.

Note that if the printed subject matter of claims 48-50 were present in the independent claim, where each of claims 48-50 represented a member of a Markush grouping, there would be no further grounds of objection because the issue of proper dependency would be removed.

For the above reasons, the claims are believed to remain properly objected to.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

I Claims 1-6, 10, 16-21, 25-30 and 34-40 remain rejected under 35 U.S.C. 102(e) as being anticipated by Gumkowski et al., (U.S. Patent Application Publication No. 2006/0014788), already of record, for the reasons of record as set forth in the previous Office action at pages 13-14, which reasons are here incorporated by reference.

Applicants' remarks at pages 11-12 of their Reply have been carefully considered, but fail to persuade the Examiner of error.

Applicants have initially taken the position that the claimed subject matter is distinguished over that which is taught by Gumkowski et al. because "with food", as employed in the present specification and indicated to be "the consumption of a solid food with sufficient

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bulk and fat content that it is not rapidly dissolved and absorbed in the stomach”, (Reply at page 12, citing the specification at page 7, paragraph 23), is distinct over the allegedly minor amounts of lactose or starch formulated in the compositions of Gumkowski and further, one skilled in the art would not recognize such minor ingredients as food.

This does not persuade the Examiner for the following reasons. Words and phrases in the claims must be given their “plain meaning” as understood by one having ordinary skill in the art unless defined by Applicant in the specification with “reasonable clarity, deliberateness and precision”. (MPEP 2111.01). Here, Applicants' definition of “with food” is not reasonably clear, deliberate or precise because the definition employs the term “preferably”, (i.e., “Preferably, the food is solid...”, page 7, paragraph 23), and thus does not specify what other materials may be considered as being a food. That is, the definition is presented in a non-limiting manner. Because the specification lacks a reasonably clear, deliberate and precise definition of “with food”, the Examiner is thus directed to interpret the claim terms in a broad and reasonable manner. In the previous Office action, it was explained why the ingredients of Gumkowski met the definition of “food”. Also, Gumkowski et al. further and clearly specifies that compositions of their invention may be “mixed with an aqueous liquid and sold as pre-formed emulsions, or added to food such as ice cream.”. Such clearly meets the requirements of the present claims.

At the first paragraph of page 12 of their response, Applicants have apparently taken the position that Gumkowski et al. teach away from administering CETP inhibitors with food because, in the words of Applicants, “dependence on exposure of food could compromise the effectiveness of the medication due to a lack of patient compliance with labeling instructions”, (page 12 of the Reply, first paragraph). Upon re-reading paragraph [0012], it appears to the

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Examiner, however, that intake of the CETP inhibitors with food is encouraged, if not required. In particular, Gumkowski et al. highlight “In addition, there is minimal CETP inhibition in the absence of food due to low fasted plasma exposure. As a result, labeling would need to indicate administration with food.”. In the next sentence, Gumkowski et al. indicate that lack of compliance with labeling instructions, i.e., to take the CETP inhibitors with food, could compromise the effectiveness of the CETP inhibitors in the treatment of atherosclerosis.

Finally, Applicants take the position that Gumkowski et al. is directed to only some CETP inhibitors when they discuss administration with triglyceride solutions while the presently claimed CETP inhibitor is listed only among many other such inhibitors. The Examiner does not agree because Gumkowski et al. speaks of “some” of the inhibitors in regards to the ability of only some to display a food effect of 20-30x. In context, it appears that Gumkowski et al. indicates that while all CETP inhibitors would display a food effect, i.e., an increased AUC, (last sentence of col. 2 on page 1), some have even displayed a food effect as great as 20-30x. This does not mean that only some CETP inhibitors would display a food effect at all. The tenor of the entirety of Gumkowski et al. indicates CETP inhibitors in general and, because they specifically name it, the presently claimed CETP inhibitor.

Accordingly, for the above reasons, it is respectfully submitted that the claims remain properly rejected.

II Claims 1-10 and 16-43 remain rejected under 35 U.S.C. 102(a) as being anticipated by Shinkai et al., (U.S. Patent No. 6,426,365), already of record, for the reasons of record as set forth in the previous Office action at pages 15-16, which reasons are here incorporated by reference.

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In attempting to refute the present finding of anticipation, Applicants take the position taken above respecting the intended meaning of “with food”, as set forth in the present specification. In particular, that “with food” would not mean the lactose or starch materials, or their amounts, as employed in Shinkai et al. In response, the Examiner takes the position as taken above. In particular, words and phrases in the claims must be given their “plain meaning” as understood by one having ordinary skill in the art unless defined by Applicant in the specification with “reasonable clarity, deliberateness and precision”. (MPEP 2111.01). Here, Applicants' definition of “with food” is not reasonably clear, deliberate or precise because the definition employs the term “preferably”, (i.e., “Preferably, the food is solid...”, page 7, paragraph 23), and thus does not specify what other materials may be considered as being a food. That is, the definition is presented in a non-limiting manner. Because the specification lacks a reasonably clear, deliberate and precise definition of “with food”, the Examiner is thus directed to interpret the claim terms in a broad and reasonable manner. In the previous Office action, it was explained why the ingredients of Shinkai et al. meet the definition of “food”. As such, the teachings of Shinkai et al. clearly meet the requirements of the present claims and thus, the rejection is respectfully deemed to remain proper.

Claim Rejection - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-6, 10-21, 25-30, 34-40 and 44-50 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gumkowski et al., (U.S. Patent Application Publication No. 2006/0014788), or claims 1-53 remain rejected under 35 U.S.C. 103(a) as being unpatentable

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over Shinkai et al., (U.S. Patent No. 6,426,365), either in view of Remington's Pharmaceutical Sciences, ("Remington's"), each of record, for the reasons of record as set forth in the previous Office action at pages 16-20, which reason are here incorporated by reference.

Applicants' remarks have been carefully considered, but fail to persuade the Examiner of error in his determination of obviousness.

Here, Applicants have argued against Gumkowski et al. as above, by taking the position that Gumkowski et al. teach away from administering CETP inhibitors with food because, in the words of Applicants, "dependence on exposure of food could compromise the effectiveness of the medication due to a lack of patient compliance with labeling instructions", (page 12 of the Reply, first paragraph). As above, upon re-reading paragraph [0012], it appears to the Examiner, however, that intake of the CETP inhibitors with food is encouraged, if not required. In particular, Gumkowski et al. highlight "In addition, there is minimal CETP inhibition in the absence of food due to low fasted plasma exposure. As a result, labeling would need to indicate administration with food.". In the next sentence, Gumkowski et al. indicate that lack of compliance with labeling instructions, i.e., to take the CETP inhibitors with food, could compromise the effectiveness of the CETP inhibitors in the treatment of atherosclerosis.

Also, Applicants again argue that one skilled in the art would not recognized the lactose and starch of Shinkai et al. as food because of the "with food" requirement of the present claims. Again, this is not persuasive because of the reasons presented above. In particular, words and phrases in the claims must be given their "plain meaning" as understood by one having ordinary skill in the art unless defined by Applicant in the specification with "reasonable clarity, deliberateness and precision". (MPEP 2111.01). Here, Applicants' definition of "with food" is

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not reasonably clear, deliberate or precise because the definition employs the term “preferably”, (i.e., “Preferably, the food is solid...”, page 7, paragraph 23), and thus does not specify what other materials may be considered as being a food. That is, the definition is presented in a non-limiting manner. Because the specification lacks a reasonably clear, deliberate and precise definition of “with food”, the Examiner is thus directed to interpret the claim terms in a broad and reasonable manner. In the previous Office action, it was explained why the ingredients of Shinkai et al. meet the definition of “food”. As such, the teachings of Shinkai et al. clearly meet the requirements of the present claims and thus, the rejection is respectfully deemed to remain proper.

Applicants have not argued against the Examiner’s finding of fact based on the Remington’s reference and conclusions of law drawn therefrom. Instead, Applicants contend that because of the supposed deficiencies of Gumkowski et al. and/or Shinkai et al., the presently claimed subject matter would not have been obvious, even in light of the teachings of Remingtons. However, for the above reasons, the Examiner cannot agree with Applicants’ assessment of either Gumkowski et al. or Shinkai et al. and thus maintains the instant rejection is proper.

Double Patenting

I Claims 1-53 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,426,365 (Shinkai et al., cited by Applicants, see the IDS filed April 12, 2004, cit. “AA”), claims 1-17 of U.S. Patent No. 6,753,346, (Shinkai et al., cited by Applicants, see IDS filed October 13, 2004, Doc. No. “BT”), **or provisionally rejected** on the grounds of nonstatutory obviousness-type double patenting as

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being unpatentable over claims 1-18 of U.S. Patent Application No. 10/825,531, (Attorney Docket listed as 06501-036002 and which has an assignee common to the present application, i.e., Japan Tobacco) for the reasons of record as set forth in the previous Office action at pages 20-22, which reasons are here incorporated by reference.

Applicants arguments have been carefully considered, but fail to persuade the Examiner of error in his determination.

Applicants have argued that the present rejections are not proper because the patented and co-pending claims are directed to compounds which embrace the compound of the present claims, and as such, do not teach the presently claimed methods.

In response, the Examiner believes the present rejections to be proper because in practicing the subject matter of the present claims, one would be practicing the subject matter of the patented or co-pending claims. A two-way test of obviousness is not required here because the present application is the later filed document involved. Thus, it is immaterial that the patented or co-pending claims do not make obvious the presently claimed methods or other subject matter where food is required.

Accordingly, the claims are deemed properly rejected.

II Claims 1-53 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 11-23 of co-pending Application No. 10/802,220 *or* claims 1-5, 7-32, 34-52, 54-83 of co-pending Application No. 10/835,916, each of record, for the reasons of record as set forth in the previous Office action at pages 22-24, which reasons are here incorporated by reference.

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Applicants have considered the present, provisional rejection and have decided to address such rejections at the time the cited applications issue as patents. Insofar as arguments pointing out any alleged errors in the present rejection, or a terminal disclaimer, have been presented, the rejection is deemed properly maintain.

None of the claims are currently in condition for allowance.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

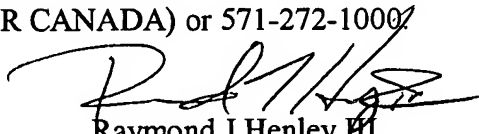
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Raymond J Henley
Primary Examiner
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August 20, 2006